of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* D&C Red No. 36 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Volatile matter at 135 °C (275 °F), not more than 1.5 percent.
Matter insoluble in toluene, not more than 1.5 percent.
2-Chloro-4-nitrobenzenamine, not more than 0.3 percent.
2-Naphthalenol, not more than 1 percent.
2,4-Dinitrobenzenamine, not more than 0.02 percent.
1-[(2,4-Dinitrophenyl)azo]-2-naphthalenol, not more than 0.5 percent.
4-[(2-Chloro-4-nitrophenyl)azo]-1-naphthalenol, not more than 0.5 percent.
1-[(4-Nitrophenyl)azo]-2-naphthalenol, not more than 0.3 percent.
1-[(4-Chloro-2-nitrophenyl)azo]-2-naphthalenol, not more than 0.3 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 95 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 36 may be safely used for coloring ingested drugs, other than mouthwashes and dentifrices, in amounts not to exceed 1.7 milligrams per daily dose of the drug for drugs that are taken continuously only for less than 1 year. For drugs taken continuously for longer than 1 year, the color additive shall not be used in amounts to exceed 1.0 milligram per daily dose of the drug. D&C Red No. 36 may be safely used for coloring externally applied drugs in amounts consistent with current good manufacturing practice.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of §70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 36 shall be certified in accordance with regulations in part 80 of this chapter.

[53 FR 29031, Aug. 2, 1988; 53 FR 35255, Sept. 12, 1988, as amended at 53 FR 52130, Dec. 27, 1988]

§74.1339 D&C Red No. 39.

(a) *Identity.* (1) The color additive D&C Red No. 39 is *o*-[*p*(β,β′-dihydroxy-diethylamino)-phenylazo]-benzoic acid.

(2) Color additive mixtures made with D&C Red No. 39 may contain the following diluents: Water, acetone, isopropyl alcohol, and specially denatured alcohols used in accordance with 26 CFR part 212.

(b) *Specifications.* D&C Red No. 39 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 100 °C.), not more than 2.0 percent.
Matter insoluble in acetone, not more than 1.0 percent.
Anthranilic acid, not more than 0.2 percent.
N,*N*-(β,β′-Dihydroxy-diethyl) aniline, not more than 0.2 percent.
Subsidiary colors, not more than 3.0 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 95.0 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 39 may be safely used for the coloring of quaternary ammonium type germicidal solutions intended for external application only, and subject to the further restriction that the quantity of the color additive does not exceed 0.1 percent by weight of the finished drug product.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of §70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 39 shall be certified in accordance with regulations promulgated under part 80 of this chapter.

§74.1340 FD&C Red No. 40.

(a) *Identity and specifications.* (1) The color additive FD&C Red No. 40 shall